Patent No. 6,949563 OS-10001



#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:

Graham Michael WYNNE et al.

Patent No.:

6,949,563 BZ

Application No.:

10/752,342 Attorney Docket No.: OS-10001

Filed:

January 06, 2004

Confirmation No.:

4508

Examiner:

Susannah E. LEE

Title:

(2-CARBOXAMIDO)(3-

**AMINOTHIOPHENE** 

**COMPOUNDS** 

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Certificate of Corrections Branch, Commissioner for Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, on the date appearing below.

OSI Pharmaceuticals, Inc.

BY 1<sup>ST</sup> CLASS MAIL

Attention: Certificate of Corrections Branch

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Certificate

of Correction

# REQUEST FOR EXPEDITED ISSUANCE OF CERTIFICATE OF **CORRECTION – ERROR ATTRIBUTED TO OFFICE UNDER 37 CFR 1.322**

Applicants respectfully request that an error in U.S. Patent No. 6,949,63 be made of record and that Commissioner expedite the issuance of a Certificate of Correction.

Applicants noticed a mistake in U.S. Pat. No. 6,949,563 incurred through the fault of the Patent and Trademark Office in column 34, line 20, in which the term "lunch" should have shown --lung-- instead. In order to request expedited issuance of the Certificate of Correction, Applicants provide documentation which clearly discloses in the records of the Office that supports Applicants' assertion. This is shown in a Notice of Allowability (8 pages, Paper No. 033005) mailed on April 5, 2005 in which Examiner included an Interview Summary agreeing to an Examiner's Amendment to add to claim 15 the terms "lung...cancer". The terms "lung...cancer" was included in originally presented and now canceled claim 20 which depended on claim 15.

No fee should be required for this Request for Expedited Issuance of Certificate of Correction due to error attributed to the Office; however, Commissioner is authorized to charge any deficiencies and credit any overpayment to OSI Pharmaceuticals, Inc. Deposit Account No. 50-2783.

Agent for Applicants can be reached at the telephone number and address below.

Very truly yours,

Mm7. Mywyr Kim T. Nguyen

Agent for Assignee

Registration No. 47,821

Telephone (631) 962-2089

Fax (631) 752-3880

November 4, 2005 OSI Pharmaceuticals, Inc. 58 South Service Road, Suite 110 Melville, NY 11747



Docket #: OS-10001

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:

Graham Michael WYNNE et al.

Patent No.:

6,949,563 **B** 2\_10/752,342

Application No.:

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January 06, 2004

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4508

Examiner:

Susannah E. LEE

Title:

(2-CARBOXAMIDO)(3-AMINOTHIOPHENE COMPOUNDS

**Attention: Certificate of Corrections Branch** 

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

# 1<sup>st</sup> CLASS MAIL CERTIFICATE OF MAILING under 37 CFR 1.8 FOR ABOVE IDENTIFIED APPLICATION

- 1) Request for Expedited Issuance of Certificate of Correction (2 pages)
- 2) Certificate of Correction, Form PTO/SB/44 (1 page)
- 3) Copy of Notice of Allowability mailed April 5, 2005 (8 pages)
- 4) Certificate of Mailing under 37 CFR 1.8 (1 page)
- 5) return receipt postcard

are being deposited to the United States Postal Service "1<sup>st</sup> Class Mail Post Office to Addressee" service under 37 C.F.R. §1.8 on November 4, 2005 and is addressed to Attention: Certificate of Corrections Branch, Commissioner of Patents, P.O. Box 1450, Alexandria, VA, 22313-1450.

Printed Name:

Kim T. Nguyen

Respectfully Submitted,

Registration No. 4/7,821

Agent for Applicant

OSI Pharmaceuticals, Inc. 58 S. Service Rd Suite 110

Melville, NY 11747

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. (Also Form PTO-1050)

# UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION	
PATENT NO. : 6,949,563 62	Page 1 of 1
APPLICATION NO.: 10/752,342	
ISSUE DATE : September 27, 2005	
INVENTOR(S) : Graham Michael WYNNE et al.	
It is certified that an error appears or errors appear in the above-identified patent and th is hereby corrected as shown below:	at said Letters Patent
Column 34, line 20, "lunch" should be changed tolung	

MAILING ADDRESS OF SENDER (Please do not use customer number below):

OSI Pharmaceuticals, Inc.

58 South Service Road, Suite 110, Melville, NY 11747

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

OFE WAY		
NOV 1 0 2005 W	Application No.	Applicant(s)
NOV I	10/752,342	WYNNE ET AL.
Notice of Allowability	Examiner	Art Unit
Washington and the same of the	Susannah Lee	1626
The MAILING DATE of this communication all claims being allowable, PROSECUTION ON THE MERIT erewith (or previously mailed), a Notice of Allowance (PTO IOTICE OF ALLOWABILITY IS NOT A GRANT OF PATE of the Office or upon petition by the applicant. See 37 CFR	S IS (OR REMAINS) CLOSED in L-85) or other appropriate commu NT RIGHTS. This application is s 1.313 and MPEP 1308.	this application. If not included nication will be mailed in due course. THI
. This communication is responsive to Applicant's Rem	arks filed on 3/11/05.	
. Mathematical The allowed claim(s) is/are 1-15 and 21 renumbered	<u>as 1-16</u> .	
s.   The drawings filed on are accepted by the Example 1.	miner.	
a) Acknowledgment is made of a claim for foreign prior a) All b) Some* c) None of the:  1. Certified copies of the priority documents	have been received.	
<ol> <li>Certified copies of the priority documents</li> <li>Copies of the certified copies of the priori</li> </ol>		
'	ty documents have been received	in this national stage application from the
International Bureau (PCT Rule 17.2(a)).  * Certified copies not received:		•
noted below. Failure to timely comply will result in ABAND THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  A SUBSTITUTE OATH OR DECLARATION must be INFORMAL PATENT APPLICATION (PTO-152) which	submitted. Note the attached EXA	
CORRECTED DRAWINGS ( as "replacement sheets"	•	•
(a) ☐ including changes required by the Notice of Draft		( PTO-948) attached
1) hereto or 2) to Paper No./Mail Date	•	(, , , , , , , , , , , , , , , , , , ,
(b) including changes required by the attached Exam Paper No./Mail Date	<del></del>	in the Office action of
Identifying Indicia such as the application number (see 37 (each sheet. Replacement sheet(s) should be labeled as suc		
DEPOSIT OF and/or INFORMATION about the cattached Examiner's comment regarding REQUIREM		
	5 □ Notice of In	ormal Patent Application (PTO-152)
	J. L. NORCE OF IN	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Notice of References Cited (PTO-892)	348) 6 🕅 Interview Si	
<ul> <li>☑ Notice of References Cited (PTO-892)</li> <li>☐ Notice of Draftperson's Patent Drawing Review (PTO-1992)</li> <li>☐ Information Disclosure Statements (PTO-1449 or PTO-1992)</li> </ul>	Paper No./	Mail Date <u>033005</u> . Amendment/Comment
<ul> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftperson's Patent Drawing Review (PTO-15)</li> <li>Information Disclosure Statements (PTO-1449 or PTO Paper No./Mail Date</li> </ul>	Paper No./ /SB/08), 7. ⊠ Examiner's	Mail Date <u>033005</u> . Amendment/Comment
Attachment(s)  . ☑ Notice of References Cited (PTO-892)  . ☑ Notice of Draftperson's Patent Drawing Review (PTO-992)  . ☑ Information Disclosure Statements (PTO-1449 or PTO Paper No./Mail Date  . ☑ Examiner's Comment Regarding Requirement for Dep of Biological Material	Paper No./ /SB/08), 7. ⊠ Examiner's	Mail Date <u>033005</u> . Amendment/Comment Statement of Reasons for Allowance



# Interview Summary

Application No.	Applicant(s)		
10/752,342	WYNNE ET AL.		
Examiner	Art Unit	_	
Susannah Lee	1626		

TRANS	Susannah Le	e	1626	•
All participants (applicant, applicant's representative, PTO	personnel):			
(1) <u>Susannah Lee</u> .	(3)			
(2) <u>Attorney Shu Lee</u> .	(4)			
Date of Interview: 29 March 2005.				
Type: a)⊠ Telephonic b)□ Video Conference c)□ Personal [copy given to: 1)□ applicant 2	2)∏ applicant	's representative	] .	
Exhibit shown or demonstration conducted: d) Yes If Yes, brief description:	e)∐ No.			
Claim(s) discussed: <u>1-21</u> .				
Identification of prior art discussed:				
Agreement with respect to the claims f)⊠ was reached. g	ı)∏ was not r	eached. h)⊡ N	<b>/A</b> .`	
Substance of Interview including description of the general reached, or any other comments: In Claim 14, p. 5, line 19, 3, insert —wherein the hyperproliferative disorder is selected cancer, neck cancer, gastrointestinal cancer, leukemia, over phrase claim 1. Delete claims 16-20.	insertand- ed from the gr	after the semicoup consisting of	colon. In Claim f breast cancer,	15, p. 5, line head
(A fuller description, if necessary, and a copy of the amend allowable, if available, must be attached. Also, where no callowable is available, a summary thereof must be attached	opy of the am			
THE FORMAL WRITTEN REPLY TO THE LAST OFFICE A INTERVIEW. (See MPEP Section 713.04). If a reply to the GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR FORM, WHICHEVER IS LATER, TO FILE A STATEMENT (Summary of Record of Interview requirements on reverse si	last Office ac THE MAILING OF THE SUB	tion has already S DATE OF THIS STANCE OF THI	been filed, APPI INTERVIEW S	LICANT IS UMMARY
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Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.		Examiner's signa	ature, if required	

Art Unit: 1626

#### **DETAILED ACTION**

Claims 1-21 are pending in this application. Claims 22-39 were canceled by supplemental amendment.

#### Response to Amendment/Remarks

Applicant's supplemental amendment filed on 03/11/2005 is acknowledged.

Applicant's remarks, see pages 7-11, filed 03/11/2005, with respect to Claims 1-14 have been fully considered and are persuasive. The rejections of Claims 1-14 have been withdrawn.

#### Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Shu Lee on 03/29/2005.

The application has been amended as follows:

In Claim 14, p. 5, line 19, insert the word ---and--- after the semicolon at the end of the line. In Claim 15, p. 5, line 3, insert ---wherein the hyperproliferative disorder is selected from the group consisting of breast cancer, head cancer, neck cancer, gastrointestinal cancer, leukemia, ovarian, bronchial, lunch or pancreatic cancer--- at the end of the sentence after the phrase claim 1.

Delete Claims 16-20.

Application/Control Number: 10/752,342

Art Unit: 1626

## Reasons for Allowance

The present invention is directed to (2-carboxamido)-3-aminothiophene compounds as

depicted in the compound of formula (I),

. The closest prior art of record is

Wood et al. (U.S. Pat. Num. 6,187,799), which teaches similar 3-aminothiophene compounds.

The difference is that in the instant application, R1 is

$$-\infty$$
F, or  $-\infty$  and  $R_2$  is

which are not taught by the prior art. Therefore, since the

prior art does not teach or suggest the instant invention it is allowed.

In addition the present invention is directed to inhibiting c-Kit proto-oncogene using the compound of formula (I). Support for this is found in Applicant's specification and the non-patent literature applicant provided. In addition, the following journal articles provide support for applicant's intended use:

Sihto, Harri et al., "KIT and Platlet-Derived Growth Factor Receptor Alpha Tyrosine Kinase Gene Mutations and KIT Amplifications in Human Solid Tumors," Journal of Clinical Oncology, Volume 23(1), 2005, pp. 49-57.

Application/Control Number: 10/752,342 Page 4

Art Unit: 1626

Potti, Anil et al., "Immunohistochemical Determination of HER-2/neu Overexpression in Malignant Melanoma Reveals No Prognostic Value, while c-KIT Overexpression Exhibits

Potential Therapeutic Implications," Journal of Carcinogenesis, Volume 2(8), 2003.

## Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Lee whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Lee Patent Examiner, AU 1626 oseph K. McKane

Supervisory Patent Examiner

AU 1626

Date: 03/31/05



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450

# NOTICE OF ALLOWANCE AND FEE(S) DUE

38724

7500

04/05/2005

OSI PHARMACEUTICALS, INC. 58 SOUTH SERVICE ROAD MELVILLE, NY 11747 EXAMINER

LEE, SUSANNAH E

ART UNIT PAPER NUMBER

1626

DATE MAILED: 04/05/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,342	01/06/2004	Graham Michael Wynne	OS-10001	4508

TITLE OF INVENTION: (2-CARBOXAMIDO)(3-AMINO)THIOPHENE COMPOUNDS

Γ	APPLN. TYPE SMALL ENTITY		ISSUE FEE PUBLICATION FEE		TOTAL FEE(S) DUE	DATE DUE
	nonprovisional	nonprovisional NO \$1400		\$300	\$1700	07/05/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED</u>. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

#### **HOW TO REPLY TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

Complete and send this form, together with applicable fee(s), to: Mail

Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (703) 746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block I for any change of address)			Feeis	Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying			
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MELVILLE, NY 1	1/4/			trans	issed to the Mai mitted to the USF	his Fee(s) Transmittal is bein with sufficient postage for fir il Stop ISSUE FEE address PTO (703) 746-4000, on the o	date indicated below.
							(Depositor's name)
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APPLICATION NO.	FILING DATE	F	TRST NAME	D INVENTOR		ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,342	01/06/2004		Graham Mic	hael Wynne		OS-10001	4508
TITLE OF INVENTION: (2	-CARBOXAMIDO)(3-AMI	NO)THIOPHENE	COMPOUR	NDS			
APPLN, TYPE	SWALL ENTITY	ISSUE FE	:E	DI IDI IC	ATION FEE	TOTAL FEE(S) DUE	DATE DUE
	SMALL ENTITY					\$1700	07/05/2005
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Address form PTO/SB/12	22) attached.		(2) the nat	(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to			
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Please check the appropriate	assignee category or catego	ries (will not be pri	nted on the p	natent):	Individual 🗖 C	orporation or other private gr	oup entity Government
4a. The following fee(s) are			Payment of				
Issue Fee			A check	in the amount	of the fee(s) is en	closed.	
	mall entity discount permitte		Payment by credit card. Form PTO-2038 is attached.				
Advance Order - # of	Copies		The Director is hereby authorized by charge the required fee(s), or credit any overpayment, Deposit Account Number(enclose an extra copy of this form).				
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The Director of the USPTO i NOTE: The Issue Fee and Printerest as shown by the reco	s requested to apply the Issu ublication Fee (if required) wards of the United States Pate	e Fee and Publicati vill not be accepted int and Trademark (	on Fee (if an from anyone Office.	y) or to re-app e other than th	oly any previousl e applicant; a reg	y paid issue fee to the application is treed attorney or agent; or the	ation identified above. he assignee or other party in
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# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.nspto.gov

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,342 01/06/2004		Graham Michael Wynne	OS-10001	4508
38724	7590 04/05/2005		EXAM	INER
	CEUTICALS, INC.		LEE, SUSANNAH E	
58 SOUTH SERV MELVILLE, NY			ART UNIT	PAPER NUMBER
WEELVIELD, IVI			1626	
			DATE MAILED: 04/05/200	5

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.